House Study Bill 685 - Introduced

HOUS	SE FILE
ВУ	(PROPOSED COMMITTEE ON
	HUMAN RESOURCES BILL BY
	CHAIRPERSON LUNDGREN)

A BILL FOR

- 1 An Act related to pharmacy benefits managers and prescription
- 2 drug prices, and including applicability provisions.
- 3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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- 1 Section 1. Section 510B.1, Code 2020, is amended to read as 2 follows:
- 3 510B.1 Definitions.
- As used in this chapter, unless the context otherwise
- 5 requires:
- 6 1. "Biological product" means the same as defined in section
- 7 155A.3.
- 8 2. "Clean claim" means a claim that has no defect or
- 9 impropriety, including a lack of any required substantiating
- 10 documentation, or other circumstances requiring special
- 11 treatment, that prevents timely payment from being made on the
- 12 claim.
- 13 1. "Commissioner" means the commissioner of insurance.
- 2. "Covered entity" means a nonprofit hospital or medical
- 15 services corporation, health insurer, health benefit plan, or
- 16 health maintenance organization; a health program administered
- 17 by a department or the state in the capacity of provider of
- 18 health coverage; or an employer, labor union, or other group of
- 19 persons organized in the state that provides health coverage.
- 20 "Covered entity" does not include a self-funded health coverage
- 21 plan that is exempt from state regulation pursuant to the
- 22 federal Employee Retirement Income Security Act of 1974
- 23 (ERISA), as codified at 29 U.S.C. §1001 et seq.; a plan issued
- 24 for health coverage for federal employees; or a health plan
- 25 that provides coverage only for accidental injury, specified
- 26 disease, hospital indemnity, Medicare supplemental, disability
- 27 income, or long-term care, or other limited benefit health
- 28 insurance policy or contract.
- 29 3. "Covered individual" means a member, participant,
- 30 enrollee, contract holder, policyholder, or beneficiary of a
- 31 covered entity who is provided health coverage by the covered
- 32 entity, and includes a dependent or other person provided
- 33 health coverage through a policy, contract, or plan for a
- 34 covered individual.
- 35 4. "Generic drug" means a chemically equivalent copy of a

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- 1 brand-name drug with an expired patent.
- 2 5. "Labeler" means a person that receives prescription
- 3 drugs from a manufacturer or wholesaler and repackages those
- 4 drugs for later retail sale and that has a labeler code from
- 5 the federal food and drug administration pursuant to 21 C.F.R.
- 6 §207.20.
- 7 6. "Maximum reimbursement amount" means the maximum
- 8 reimbursement amount for a therapeutically and pharmaceutically
- 9 equivalent multiple-source prescription drug that is listed in
- 10 the most recent edition of the publication entitled "Approved
- 11 Drug Products with Therapeutic Equivalence Evaluations",
- 12 published by the United States food and drug administration,
- 13 otherwise known as the orange book.
- 4. "Contracted pharmacy" means a pharmacy that participates
- 15 in a pharmacy benefits manager's network through a contract
- 16 with any of the following:
- 17 a. A pharmacy benefits manager.
- 18 b. A pharmacy services administration organization.
- 19 c. A pharmacy group purchasing organization.
- 20 5. "Cost-sharing" means any coverage limit, copayment,
- 21 coinsurance, deductible, or other out-of-pocket expense
- 22 obligation imposed on a covered person by a health benefit plan
- 23 providing for third-party payment or prepayment of health or
- 24 medical expenses.
- 25 6. "Covered person" means a policyholder, subscriber, or
- 26 other person participating in a health benefit plan that covers
- 27 prescription drugs.
- 7. "Drug" means all medicines and preparations recognized
- 29 in the official United States Pharmacopeia or the official
- 30 National Formulary as substances intended to be used for the
- 31 care, mitigation, or prevention of disease.
- 32 8. "Generically equivalent drug" means a drug that is
- 33 pharmaceutically and therapeutically equivalent to a drug that
- 34 is prescribed.
- 9. "Health benefit plan" means the same as defined in

- 1 section 514J.102.
- 2 10. "Health care professional" means the same as defined in
- 3 section 514J.102.
- 4 ll. "Health carrier" means the same as defined in section
- 5 514J.102.
- 6 12. "Maximum allowable cost list" means a list of drugs
- 7 or other methodology used by a pharmacy benefits manager,
- 8 directly or indirectly, setting the maximum allowable payment
- 9 to a pharmacy for a generic drug, brand-name drug, biological
- 10 product, or other prescription drug. "Maximum allowable cost
- 11 list" includes without limitation all of the following:
- 12 a. Average acquisition cost, including the national average
- 13 drug acquisition cost.
- 14 b. Average manufacturer price.
- 15 c. Average wholesale price.
- 16 d. Brand effective rate.
- 17 e. Generic effective rate.
- 18 f. Discount indexing.
- 19 g. Federal upper limits.
- 20 h. Wholesale acquisition cost.
- 21 i. Any other term that a pharmacy benefits manager or a
- 22 health carrier may use to establish reimbursement rates to a
- 23 pharmacy for pharmacist services.
- 24 13. "Pharmaceutically equivalent" means drugs that have
- 25 identical amounts of the same active chemical ingredients in
- 26 the same dosage form and that meet the identical, compendious,
- 27 or other applicable standards of strength, quality, and purity
- 28 according to the official United States Pharmacopeia or other
- 29 nationally recognized compendium.
- 30 14. "Pharmacist services" means products, goods, and
- 31 services, or any combination of products, goods, and services,
- 32 provided as part of the practice of pharmacy.
- 33 7. 15. "Pharmacy" means pharmacy the same as defined in
- 34 section 155A.3.
- 35 16. "Pharmacy acquisition cost" means the amount that a

- 1 pharmaceutical wholesaler charges for a drug as listed on the
- 2 pharmacy's billing invoice.
- 3 17. "Pharmacy benefits manager affiliate" means a pharmacy
- 4 or pharmacist that directly or indirectly, through one or more
- 5 intermediaries, owns or controls, is owned or controlled by, or
- 6 is under common ownership or control with a pharmacy benefits
- 7 manager.
- 8 8. 18. "Pharmacy benefits management services" means the
- 9 administration or management of prescription drug benefits
- 10 provided by a covered entity under the terms and conditions
- 11 of the contract between the pharmacy benefits manager and the
- 12 covered entity. provision of any of the following services on
- 13 behalf of a health carrier:
- 14 a. The procurement of prescription drugs at a negotiated
- 15 rate for dispensing within this state.
- 16 b. The processing of prescription drug claims.
- 17 c. The administration of payments related to prescription
- 18 drug claims.
- 20 performs pharmacy benefits management services, pursuant to a
- 21 contract or other relationship with a health carrier, either
- 22 directly or through an intermediary, provides pharmacy benefits
- 23 management services for a health carrier. "Pharmacy benefits
- 24 manager" includes a person acting on behalf of a pharmacy
- 25 benefits manager in a contractual or employment relationship in
- 26 the performance of pharmacy benefits management services for a
- 27 covered entity. "Pharmacy benefits manager" does not include
- 28 a health insurer licensed in the state if the health insurer
- 29 or its subsidiary is providing pharmacy benefits management
- 30 services exclusively to its own insureds, or a public
- 31 self-funded pool or a private single employer self-funded
- 32 plan that provides such benefits or services directly to its
- 33 beneficiaries.
- 34 20. "Pharmacy services administrative organization" means
- 35 an organization that assists pharmacies, pharmacy benefits

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- 1 managers, or third-party payers in achieving administrative
- 2 efficiencies, including contracting and payment efficiencies.
- 3 10. 21. "Prescription drug" means prescription drug the
- 4 same as defined in section 155A.3.
- 5 11. 22. "Prescription drug order" means prescription drug
- 6 order the same as defined in section 155A.3.
- 7 23. "Spread pricing" means a model of prescription drug
- 8 pricing in which a pharmacy benefits manager charges a health
- 9 benefit plan a contracted price for a prescription drug, and
- 10 the contracted price for the prescription drug differs from the
- 11 amount the pharmacy benefits manager directly or indirectly
- 12 pays a pharmacy for the same prescription drug.
- 13 24. "Therapeutically equivalent" means drugs from the same
- 14 therapeutic class that if administered in appropriate amounts
- 15 will provide the same therapeutic effect, identical in duration
- 16 and intensity.
- 17 Sec. 2. Section 510B.2, Code 2020, is amended to read as
- 18 follows:
- 19 510B.2 Certification as a third-party administrator required.
- 20 A pharmacy benefits manager doing business in this state
- 21 shall obtain a certificate of registration as a third-party
- 22 administrator under chapter 510 pursuant to section 510.21, and
- 23 the provisions relating to a third-party administrator pursuant
- 24 to chapter 510 shall apply to a pharmacy benefits manager.
- Sec. 3. Section 510B.4, Code 2020, is amended to read as
- 26 follows:
- 27 510B.4 Performance of duties good faith conflict of
- 28 interest.
- 29 1. A pharmacy benefits manager shall perform the pharmacy
- 30 benefits manager's duties exercising exercise good faith and
- 31 fair dealing in the performance of its the pharmacy benefits
- 32 manager's contractual obligations toward the covered entity a
- 33 health carrier or a pharmacy.
- 34 2. A pharmacy benefits manager shall notify the covered
- 35 entity a health carrier or a pharmacy in writing of any

- 1 activity, policy, practice ownership interest, or affiliation
- 2 of the pharmacy benefits manager that presents any conflict of
- 3 interest.
- 4 Sec. 4. Section 510B.5, Code 2020, is amended to read as
- 5 follows:
- 6 510B.5 Contacting covered individual requirements.
- 7 A pharmacy benefits manager, unless authorized pursuant to
- 8 the terms of its contract with a covered entity health carrier,
- 9 shall not contact any covered individual person without
- 10 the express written permission of the covered entity health
- 11 carrier.
- 12 Sec. 5. Section 510B.6, Code 2020, is amended to read as
- 13 follows:
- 14 510B.6 Dispensing of substitute prescription drug for
- 15 prescribed drug drugs.
- 16 l. The following provisions shall apply when if a pharmacy
- 17 benefits manager requests the dispensing of a substitute
- 18 prescription drug for a prescribed prescription drug prescribed
- 19 to a covered individual person:
- 20 a. The pharmacy benefits manager may request the
- 21 substitution of a lower priced generic and therapeutically
- 22 equivalent prescription drug for a higher priced prescribed
- 23 prescription drug.
- 24 b. If the substitute prescription drug's net cost to
- 25 the covered individual person or covered entity the health
- 26 carrier exceeds the cost of the prescribed prescription drug,
- 27 the substitution shall be made only for medical reasons that
- 28 benefit the covered individual person as determined by the
- 29 covered person's prescribing health care professional.
- 30 2. A pharmacy benefits manager shall obtain the approval of
- 31 the prescribing practitioner health care professional prior to
- 32 requesting any substitution under this section.
- 33 3. A pharmacy benefits manager shall not substitute an
- 34 equivalent prescription drug contrary to a prescription drug
- 35 order that prohibits a substitution.

- 1 Sec. 6. Section 510B.7, Code 2020, is amended by striking
- 2 the section and inserting in lieu thereof the following:
- 3 510B.7 Health carrier termination of contract notice.
- 4 If a pharmacy benefits manager receives notice from a health
- 5 carrier of termination of the health carrier's contract with
- 6 the pharmacy benefits manager, the pharmacy benefits manager
- 7 shall notify all contracted pharmacies of the effective date
- 8 of the termination within ten working days of receipt of the
- 9 notice.
- 10 Sec. 7. Section 510B.8, Code 2020, is amended by striking
- 11 the section and inserting in lieu thereof the following:
- 12 510B.8 Maximum allowable cost lists requirements.
- 13 l. Before a pharmacy benefits manager places or continues a
- 14 particular drug on a maximum allowable cost list, all of the
- 15 following requirements must be satisfied:
- 16 a. If the drug is a generically equivalent drug, the
- 17 drug shall be listed as therapeutically equivalent and
- 18 pharmaceutically equivalent "A" or "B" rated in the most recent
- 19 edition of the publication entitled "Approved Drug Products
- 20 with Therapeutic Equivalence Evaluations", published by the
- 21 United States food and drug administration, otherwise known as
- 22 the orange book, or have an NR or NA rating by a nationally
- 23 recognized reference.
- 24 b. The drug shall be available for purchase by each pharmacy
- 25 in this state from a national or regional wholesaler licensed
- 26 pursuant to section 155A.17.
- 27 c. The drug shall not be obsolete.
- 28 2. A pharmacy benefits manager shall comply with all of the
- 29 following requirements:
- 30 a. The pharmacy benefits manager must provide each pharmacy
- 31 subject to a maximum allowable cost list access to the maximum
- 32 allowable cost list.
- 33 b. The pharmacy benefits manager must update the maximum
- 34 allowable cost list within seven calendar days of any of the
- 35 following dates:

- 1 (1) The date of an increase in the pharmacy acquisition 2 cost.
- 3 (2) The date of a change in the methodology on which the 4 maximum allowable cost list is based.
- 5 (3) The date of a change in any value of any variable
- 6 involved in the methodology on which the maximum allowable cost
- 7 list is based.
- 8 c. The pharmacy benefits manager must provide a process
- 9 for each pharmacy subject to the maximum allowable cost list
- 10 to receive prompt notification of any update to the maximum
- ll allowable cost list.
- 12 d. The pharmacy benefits manager shall not reimburse any
- 13 pharmacy in this state for a prescription drug in an amount
- 14 less than the amount that the pharmacy benefits manager
- 15 reimburses a pharmacy benefits manager affiliate for providing
- 16 the same prescription drug. The amount shall be calculated on
- 17 a per unit basis based on the same generic product identifier
- 18 or generic code number.
- 19 3. A pharmacy may decline to provide pharmacist services
- 20 to a pharmacy benefits manager or to a covered person if, as a
- 21 result of a maximum allowable cost list, a pharmacy is to be
- 22 paid less than that pharmacy's pharmacy acquisition cost for
- 23 the pharmacist services.
- 24 Sec. 8. <u>NEW SECTION</u>. 510B.8A Maximum allowable cost lists appeal procedure.
- 26 1. A pharmacy benefits manager shall provide an appeal
- 27 procedure to allow a pharmacy to challenge a maximum allowable
- 28 cost list, and any reimbursement made under a maximum allowable
- 29 cost list, for a specific drug for any of the following
- 30 reasons:
- 31 a. Failure to meet the requirements of section 510B.8.
- 32 b. The maximum allowable cost falls below the pharmacy
- 33 acquisition cost.
- 34 2. The appeal procedure shall include all of the following:
- 35 a. A dedicated telephone number, email address, and internet

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- 1 site for the pharmacy to submit appeals.
- b. The ability to submit an appeal directly to the
- 3 pharmacy benefits manager or directly to the pharmacy service
- 4 administration organization.
- 5 c. A time limit of no less than thirty business days to
- 6 submit an appeal from the date of any of the following:
- 7 (1) Access to a maximum allowable cost list pursuant to
- 8 section 510B.8, subsection 2, paragraph "a".
- 9 (2) A reimbursement that falls below the pharmacy
- 10 acquisition cost for a drug.
- 11 3. A pharmacy benefits manager shall respond in writing to
- 12 a pharmacy's appeal within ten business days of the date of
- 13 receipt of the appeal.
- 14 4. If a pharmacy benefits manager upholds a pharmacy's
- 15 appeal, the pharmacy benefits manager shall comply with all of
- 16 the following:
- 17 a. The pharmacy benefits manager shall permit the
- 18 challenging pharmacy to reverse and rebill the claim in
- 19 question.
- 20 b. The pharmacy benefits manager shall make a change in the
- 21 maximum allowable cost list for the drug that is the subject of
- 22 the appeal so that the reimbursement for such drug is at least
- 23 equal to the pharmacy acquisition cost.
- c. The pharmacy benefits manager shall provide the pharmacy
- 25 with the national drug code that is the basis for the increase
- 26 or change in the price of the drug.
- 27 d. The pharmacy benefits manager shall make the changes
- 28 pursuant to paragraphs a and b immediately effective for all
- 29 similarly situated pharmacies in this state.
- 30 5. If a pharmacy benefits manager denies a pharmacy's
- 31 appeal, the pharmacy benefits manager shall comply with all of
- 32 the following:
- 33 a. The pharmacy benefits manager shall provide the appealing
- 34 pharmacy the national drug code and the name of a national or
- 35 regional wholesaler licensed pursuant to section 155A.17 that

- 1 has the drug currently in stock at a price below the maximum
- 2 allowable cost list.
- 3 b. If the national drug code provided by the pharmacy
- 4 benefits manager is not available pursuant to paragraph
- 5 "a", the pharmacy benefits manager shall adjust the maximum
- 6 allowable cost list for the drug that is the basis of the
- 7 appeal to a price greater than the appealing pharmacy's
- 8 pharmacy acquisition cost for that drug, and permit the
- 9 appealing pharmacy to reverse and rebill each claim affected
- 10 by the pharmacy's inability to procure the drug at a cost that
- 11 is equal to or less than the previously challenged maximum
- 12 allowable cost.
- 13 Sec. 9. NEW SECTION. 510B.8B Prohibited actions and
- 14 activities.
- 15 1. A pharmacy benefits manager or a health carrier shall
- 16 not, as a condition of payment, reimbursement, or network
- 17 participation, require any of the following of a pharmacy:
- 18 a. To meet accreditation, certification, or credentialing
- 19 standards that are inconsistent with, more stringent than, or
- 20 in addition to the federal and state requirements applicable to
- 21 a pharmacy in this state.
- 22 b. To satisfy any insurance, surety bond, or other
- 23 financial quarantee requirements that are inconsistent with,
- 24 more stringent than, or in addition to the federal and state
- 25 requirements applicable to a pharmacy in this state.
- 26 2. A pharmacy benefits manager or a health carrier shall not
- 27 directly or indirectly charge or hold a pharmacy responsible
- 28 for a fee related to a claim in any of the following
- 29 circumstances:
- 30 a. The fee is not readily apparent to the pharmacy at the
- 31 time the pharmacy submits the claim.
- 32 b. The fee is not reported on the remittance advice of an
- 33 adjudicated claim.
- 34 c. The fee is not processed at the time a claim is
- 35 adjudicated at the point of sale.

- 3. A pharmacy benefits manager is prohibited from
 2 conducting spread pricing in this state.
- 3 4. A pharmacy benefits manager shall not terminate a
- 4 contracted pharmacy solely on the basis that the contracted
- 5 pharmacy offers or provides store-direct delivery or mail
- 6 prescriptions as an ancillary service to a covered person.
- 7 Sec. 10. Section 510B.9, Code 2020, is amended to read as 8 follows:
- 9 510B.9 Submission, approval, and use of prior Prior
- 10 authorization form.
- 11 A pharmacy benefits manager shall file with and have
- 12 approved by the commissioner a single prior authorization
- 13 form as provided in section 505.26 comply with all applicable
- 14 prior authorization requirements pursuant to section 505.26.
- 15 A pharmacy benefits manager shall use the single prior
- 16 authorization form as provided in section 505.26.
- 17 Sec. 11. Section 510B.10, Code 2020, is amended by striking
- 18 the section and inserting in lieu thereof the following:
- 19 510B.10 Disclosure of lower-cost options pharmacists.
- 20 1. A pharmacy benefits manager shall not require a covered
- 21 person to make a cost-sharing payment at the point of sale
- 22 for a prescription drug in an amount that exceeds the amount
- 23 the covered person would pay for the prescription drug if the
- 24 covered person purchased the prescription drug without using
- 25 the covered person's health benefit plan.
- 26 2. A pharmacy benefits manager shall not prohibit a
- 27 contracted pharmacy from disclosing, and shall not apply a
- 28 penalty or any other type of disincentive to a contracted
- 29 pharmacy that discloses, lower-cost prescription drug options
- 30 to a covered person including those options that are available
- 31 to the covered person if the covered person purchases the
- 32 prescription drug without using the covered person's health
- 33 benefit plan.
- 34 3. Any amount paid by a covered person for a prescription
- 35 drug purchased without using the covered person's health

- 1 benefit plan pursuant to subsection 2 shall be applied to any
- 2 deductible imposed by the covered person's health benefit plan
- 3 in accordance with the covered person's health benefit plan
- 4 coverage documents.
- 5 4. Any provision of a contract that conflicts with
- 6 subsection 1 or 2 shall be void and unenforceable.
- 7 5. A violation of this section shall be an unlawful practice
- 8 and shall be a violation of section 507B.4.
- 9 Sec. 12. <u>NEW SECTION</u>. 510B.11 Clean claims retroactive
- 10 reductions.
- 11 1. After the date of receipt of a clean claim for payment
- 12 made by a contracted pharmacy, a pharmacy benefits manager
- 13 shall not retroactively reduce payment on the claim, either
- 14 directly or indirectly, through an aggregated effective rate,
- 15 direct or indirect remuneration, a quality assurance program,
- 16 or any other means, except if the claim is found not to be
- 17 a clean claim during the course of a routine audit performed
- 18 pursuant to an agreement between the pharmacy benefits manager
- 19 and the contracted pharmacy.
- If a contracted pharmacy adjudicates a claim at the point
- 21 of sale, the reimbursement amount provided to the contracted
- 22 pharmacy by the pharmacy benefits manager shall constitute a
- 23 final reimbursement amount.
- 3. Nothing in this section shall be construed to prohibit
- 25 any retroactive increase in payment to a contracted pharmacy
- 26 pursuant to a contract between a pharmacy benefits manager and
- 27 a pharmacy services administration organization, or between a
- 28 pharmacy benefits manager and a pharmacy.
- 4. A pharmacy benefits manager shall not recoup funds from a
- 30 contracted pharmacy in connection with any claims for which the
- 31 contracted pharmacy has already been paid unless the recoupment
- 32 is a result of any of the following:
- 33 a. The recoupment is otherwise permitted or required by law.
- 34 b. The recoupment is based on an audit performed pursuant
- 35 to a contract between the pharmacy benefits manager and the

- 1 contracted pharmacy.
- 2 c. The recoupment is a result of an audit performed pursuant
- 3 to a contract between the pharmacy benefits manager and a
- 4 designated pharmacy services administrative organization.
- 5. The provisions of this section shall not apply to
- 6 an investigative audit of a contracted pharmacy's records
- 7 conducted by a pharmacy benefits manager in any of the
- 8 following circumstances:
- 9 a. Fraud, waste, abuse, or other intentional misconduct is
- 10 indicated by a review of the contracted pharmacy's claims data
- ll or statements.
- 12 b. Other investigative methods utilized by the pharmacy
- 13 benefits manager indicate that the contracted pharmacy is
- 14 or has been engaged in criminal wrongdoing, fraud, or other
- 15 intentional or willful misrepresentation.
- 16 Sec. 13. NEW SECTION. 510B.12 Compensation program —
- 17 commissioner approval.
- 18 The commissioner may review and approve the compensation
- 19 program of a pharmacy benefits manager for a health carrier to
- 20 ensure that the reimbursement for pharmacist services provided
- 21 by a contracted pharmacy is fair, reasonable, and appropriate
- 22 to provide an adequate pharmacy benefits manager's network for
- 23 the health carrier.
- 24 Sec. 14. NEW SECTION. 510B.13 Rules.
- 25 The commissioner shall adopt rules pursuant to chapter 17A
- 26 to administer this chapter.
- 27 Sec. 15. NEW SECTION. 510B.14 Enforcement.
- 28 1. The commissioner shall take any enforcement action under
- 29 the commissioner's authority to enforce compliance with this
- 30 chapter.
- 31 2. After notice and hearing, the commissioner may impose
- 32 any or all of the sanctions pursuant to section 507B.7 and may
- 33 suspend or revoke a pharmacy benefits manager's certificate of
- 34 registration as a third-party administrator upon a finding that
- 35 the pharmacy benefits manager violated any of the requirements

1 of this chapter, or of chapter 510 pertaining to third-party 2 administrators.

- 3. A pharmacy benefits manager, as an agent or vendor of a 4 health carrier, is subject to the commissioner's authority to 5 conduct an examination pursuant to chapter 507. The procedures 6 set forth in chapter 507 regarding examination reports shall
- 7 apply to an examination of a pharmacy benefits manager under 8 this chapter.
- 9 4. A pharmacy benefits manager is subject to the
 10 commissioner's authority to conduct an investigation pursuant
 11 to chapter 507B. The procedures set forth in chapter 507B
 12 regarding investigations shall apply to an investigation of a
 13 pharmacy benefits manager under this chapter
- pharmacy benefits manager under this chapter.

 14 5. A pharmacy benefits manager is subject to the
 15 commissioner's authority to conduct an examination, audit,
 16 or inspection pursuant to chapter 510 for third-party
 17 administrators. The procedures set forth in chapter 510 for
 18 third-party administrators shall apply to an examination,
 19 audit, or inspection of a pharmacy benefits manager under this
 20 chapter.
- 20 chapter.
 21 6. If the commissioner conducts an examination of a pharmacy
 22 benefits manager under chapter 507; a proceeding under chapter
 23 507B; or an examination, audit, or inspection under chapter
 24 510, all information received from the pharmacy benefits
 25 manager, and all notes, work papers, or other documents
 26 related to the examination, investigation, audit, or inspection
 27 of the pharmacy benefits manager, shall be confidential
 28 records pursuant to chapter 22 and shall be accorded the same
 29 confidentiality as notes, work papers, investigatory materials,
 30 or other documents related to the examination of an insurer as
 31 provided in section 507.14.
- 32 Sec. 16. <u>NEW SECTION</u>. 510B.15 Severability.
- 33 If any provision of this chapter or the application
- 34 thereof to any person or circumstances is held invalid, the
- 35 invalidity shall not affect other provisions or applications

- 1 of the chapter which can be given effect without the invalid
- 2 provisions or application and, to this end, the provisions of
- 3 this chapter are severable.
- 4 Sec. 17. REPEAL. Section 510B.3, Code 2020, is repealed.
- 5 Sec. 18. APPLICABILITY. This Act applies to a pharmacy
- 6 benefits manager providing pharmacy benefits management
- 7 services in this state on or after the effective date of this
- 8 Act.
- 9 EXPLANATION
- The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.
- 12 This bill relates to pharmacy benefits managers and
- 13 prescription drug prices.
- "Pharmacy benefits manager" (PBM) is defined in the bill as
- 15 a person who, pursuant to a contract or other relationship with
- 16 a health carrier, either directly or through an intermediary,
- 17 provides pharmacy benefits management services for the
- 18 health carrier. "Pharmacy benefits management services" is
- 19 defined as, on behalf of a health carrier, the procurement of
- 20 prescription drugs at a negotiated rate for dispensing within
- 21 this state, the processing of prescription drug claims, or the
- 22 administration of payments related to prescription drug claims.
- 23 The bill details the requirements that must be satisfied
- 24 before a PBM places a particular drug on a maximum allowable
- 25 cost list, or continues a particular drug on a maximum
- 26 allowable cost list. "Maximum allowable cost list" (MAC list)
- 27 is defined in the bill as a list of drugs or other methodology
- 28 used by a PBM, directly or indirectly, setting the maximum
- 29 allowable payment to a pharmacy for a generic drug, brand-name
- 30 drug, biological product, or other prescription drug. A PBM
- 31 cannot place a drug on the MAC list unless the PBM first
- 32 complies with the requirements in the bill, including ensuring
- 33 that the drug is available for purchase by each pharmacy in
- 34 this state for a national or regional wholesaler licensed in
- 35 this state.

- 1 A PBM must allow a pharmacy that is subject to a MAC list
- 2 to have access to the list. The PBM is required to update a
- 3 MAC list within seven calendar days of the date of an increase
- 4 in the pharmacy acquisition cost, a change in methodology on
- 5 which the MAC is based, or a change in any value of any variable
- 6 involved in the methodology on which the MAC list is based.
- 7 The PBM must provide a pharmacy subject to a MAC list with
- 8 prompt notification of any updates to the MAC list.
- 9 The bill provides that a PBM cannot reimburse a pharmacy in
- 10 this state for a prescription drug in an amount less than the
- ll amount that the PBM reimburses a PBM affiliate for providing
- 12 the same prescription drug. A pharmacy may decline to provide
- 13 pharmacist services to a PBM or to a covered person if, as a
- 14 result of a maximum allowable cost list, a pharmacy is to be
- 15 paid less than that pharmacy's pharmacy acquisition cost for
- 16 the prescription drug.
- 17 The bill requires a PBM to provide an appeal procedure to
- 18 allow a pharmacy to challenge a maximum allowable cost list,
- 19 and any reimbursement made under a maximum allowable cost
- 20 list. The appeal procedure must include a dedicated telephone
- 21 number, email address, and internet site for a pharmacy to
- 22 submit appeals, and must include the ability to submit an
- 23 appeal directly to the PBM or directly to the pharmacy service
- 24 administration organization. Additional requirements for the
- 25 appeals process, including the PBM's obligations if an appeal
- 26 is upheld or denied, are detailed in the bill.
- 27 The bill prohibits a PBM or a health carrier from, as a
- 28 condition of payment, reimbursement, or network participation,
- 29 requiring a pharmacy to meet accreditation, certification,
- 30 or credentialing standards that are inconsistent with, more
- 31 stringent than, or in addition to the federal and state
- 32 requirements applicable to a pharmacy in this state; or
- 33 to satisfy any insurance, surety bond, or other financial
- 34 guarantee requirements that are inconsistent with, more
- 35 stringent than, or in addition to the federal and state

- 1 requirements applicable to a pharmacy in this state. The bill
- 2 also prohibits the PBM from charging or holding a pharmacy
- 3 responsible for certain fees as detailed in the bill.
- 4 A PBM or a health carrier also cannot directly or indirectly
- 5 charge or hold a pharmacy responsible for a fee related to a
- 6 claim in any of the circumstances detailed in the bill. A
- 7 PBM is additionally prohibited from conducting spread pricing
- 8 in this state. "Spread pricing" is defined as a model of
- 9 prescription drug pricing in which a PBM charges a health
- 10 benefit plan a contracted price for a prescription drug, and
- 11 the contracted price for the prescription drug differs from the
- 12 amount the PBM directly or indirectly pays a pharmacy for the
- 13 prescription drug.
- 14 The bill prohibits a PBM from terminating a contracted
- 15 pharmacy for providing direct delivery or delivery by mail for
- 16 prescriptions to covered persons.
- 17 After the date of receipt of a clean claim for payment
- 18 from a contracted pharmacy, the bill prohibits a PBM from
- 19 retroactively reducing payment on the claim, either directly
- 20 or indirectly, through an aggregated effective rate, direct
- 21 or indirect remuneration, a quality assurance program, or any
- 22 other means unless the claim is found not to be a clean claim
- 23 during the course of a routine audit performed by the PBM. The
- 24 bill provides that if a contracted pharmacy adjudicates a claim
- 25 at the point of sale, the reimbursement amount provided to the
- 26 pharmacy by the PBM is the final reimbursement amount. A PBM
- 27 cannot recoup funds from a contracted pharmacy in connection
- 28 with claims for which the pharmacy has already been paid except
- 29 in circumstances outlined in the bill.
- 30 The bill authorizes the commissioner of insurance to review
- 31 and approve the compensation program of a PBM for a health
- 32 carrier to ensure that the reimbursement for services provided
- 33 by a contracted pharmacy is fair, reasonable, and appropriate
- 34 to provide an adequate PBM network for the health carrier.
- 35 The bill requires the commissioner to adopt rules to

- 1 administer the provisions of the bill and to take any
- 2 enforcement action under the commissioner's authority to
- 3 enforce compliance with the provisions of the bill.
- 4 The bill provides that if any provision of the bill is held
- 5 invalid, the invalidity shall not affect other provisions or
- 6 applications of the bill which can be given effect without the
- 7 invalid provisions.
- 8 The bill repeals Code section 510B.3, relating to current
- 9 enforcement and rulemaking authority, and makes conforming
- 10 changes throughout Code chapter 510B.
- 11 The bill applies to a PBM providing pharmacy benefits
- 12 management services in this state on or after the effective
- 13 date of the bill.